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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,136	10/12/2000	John F. Engelhardt	875.032US1	7933

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/689,136

Applicant(s)

ENGELHARDT ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 29-87 is/are pending in the application.
- 4a) Of the above claim(s) 37-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 29-36 and 83-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18 6) ☐ Other:

DETAILED ACTION

This Office Action is a response to the Request for Continued Examination (Paper No. 16) and "Amendment and Response..." (Paper No. 19) filed in response to the Final Office Action mailed 24 December 2003 (Paper No. 14). Claims 13-28 and 37-82 have been withdrawn from consideration. Claims 1-12, 29-36 and 83-86 were considered in Paper No. 14. Claims 13-28 were canceled, claims 1-7, 9, 10, 29, 37, 47, 79, 80, 83, 85 and 86 were amended and claim 87 was added in Paper No. 19. Claims 1-12 and 29-87 are pending, and claims 1-12, 29-36 and 83-87 are under consideration.

Election/Restrictions

The requirement for cancellation of non-elected claims is withdrawn.

Response to Amendment

The claims have been amended such that they are now limited to a method to determine or detect an agent that alters adeno-associated virus transduction comprising the step of determining whether the agent alters transduction after viral binding to the cell membrane and before synthesis to an expressible form of the viral genome. In support of the amendment Applicant points to the originally filed claim 1 and the specification at page 20. It is noted for the record that support for the method as claimed is also found in Example 5, beginning on page 66, and also at page 77, line 11 through page 78, line 10.

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Claim Rejections - 35 USC § 102

Rejection of claims 1, 4, 5 and 10-12 under 35 U.S.C. § 102(b) as anticipated by Qing *et al.* is withdrawn. Qing does not teach or suggest a method comprising the step of determining whether the agent alters transduction after viral binding to the cell membrane and before synthesis to an expressible form of the viral genome.

Claim Rejections - 35 USC § 112

Rejection of claims 1-12, 29-36 and 83-86 under 35 U.S.C. 112, first paragraph, as adding matter that was not present in the originally filed disclosure is withdrawn in view of the amendments to the claims.

Rejection of claims 1-6, 9-12, 83, 84 and 86 under 35 U.S.C. 112, first paragraph, as lacking adequate written description for reasons of record in Paper No. 14 is withdrawn in view of the amendments.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 29-36 and 83-87 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are directed to a method of determining an agent that alters AAV transduction; however, the process steps set forth in claims 1 and 87 are not limited to contacting the mammalian cell with an adeno-associated virus. It is not clear whether the virus of step (a) is referring to the adeno-associated virus of the preamble because there is no definite article preceding the recitation of "virus". Amending the claim to clearly indicate that the virus of step (a) is an AAV would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A person shall be entitled to a patent unless –

Claims 1, 4, 5, 10, 12 and 87 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferrari *et al.* (1996) *J. Virol.* 70:3227-3234.

Ferrari *et al.* teaches a method comprising contacting a mammalian cell with an agent (i.e., adenovirus or a plasmid expressing adenovirus E4 ORF6) and an AAV, and determining whether the agent alters AAV transduction (see especially Figures 2 and 3 and the captions thereto). Further, Ferrari *et al.* teaches identifying whether the agent alters transduction at the point of uncoating or second-strand synthesis, which occur after viral binding to the cell membrane and before synthesis to an expressible form. It is noted that Ferrari *et al.* teaches that second-strand synthesis is required before gene expression can take place (page 3231, second full paragraph in column 2). Thus, second strand synthesis occurs before the viral genome is in an

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expressible form. If applicant intends that the claim exclude the process of second strand synthesis itself, the claim should be amended to clearly indicate that the method identifies whether the agent alters transduction after viral binding to the cell membrane and before second strand synthesis. Thus, Ferrari *et al.* teaches a method comprising all of the limitations of the instant claims 1 and 87. Ferrari *et al.* further teaches the method wherein the cell is a human cell (i.e., 293 and HeLa cell lines) according to claim 4 (bridging pages 3227-3228); wherein transduction is enhanced according to claim 5 (Figures 2 and 3); wherein the virus is a recombinant adeno-associated virus according to claim 10, which comprises a marker gene according to claim 12 (see especially the paragraph bridging columns 1 and 2 on page 3229).

The method, cell and recombinant adeno-associated virus taught by Ferrari *et al.* are the same as those taught in the instant application; therefore, the limitations of the claims are met by Ferrari *et al.*

Allowable Subject Matter

Claims 2, 3, 6-9, 11, 29-36 and 83-86 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
July 25, 2003



**JAMES KETTER
PRIMARY EXAMINER**